

K053188 REPROCESSED BALOON INFLATION DEVICEMay 4, 2006
170 days to decisionK053188 · Product code: **NKU** · Cardiovascular
Source: <https://www.510kdatabase.net/k053188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic, Balloon Inflation, Reprocessed (NKU)
Date received	Nov 15, 2005
Decision date	May 4, 2006
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed, Inc.
Location	Plymouth, MN, US
Contact	BRUCE R LESTER
510(k) history	64 submissions · 64 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053188/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026